



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration  
850 Third Avenue  
Brooklyn, NY 11232

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Frederick Grippa, President  
B-G Lobster and Shrimp Corp.  
95 South Street  
New York, NY 10038

June 4, 1999

Ref: NYK-1999-46

Dear Mr. Grippa:

On April 12-14, 1999, Food and Drug Administration (FDA) Investigator Nancy A. Saxenian performed an inspection of your seafood processing facility located at 95 South Street in New York, NY. The inspection revealed that fresh histamine forming species of fish handled at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to the *seafood processing regulations (Title 21, Code of Federal Regulations, Part 123)*, which constitute insanitary conditions whereby the fish may have been rendered injurious to health.

As we explained in previous letters to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed serious deviations from the seafood processing regulations that include, but are not limited to, the following:

- Failure to list the display of fish on ice as a critical control point in your HACCP plan for histamine forming species of fish as required by 21 CFR 123.6(c)(2).
- Failure to follow monitoring procedures specified in your written HACCP plan for histamine forming species of fish and to maintain monitoring records as required by 21 CFR 123.6(b).

Neither the above identified violations nor the Inspectional Observations (form FDA 483) given to you at the conclusion of the inspection are intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your firm is in compliance with all of the requirements of the Act and its implementing regulations. You should take prompt action to correct these violations. Failure to achieve prompt corrective action may result in further regulatory action without further notice. These actions include seizure and/or injunction.

We also wish to comment that the inspection also revealed a failure to maintain sanitation control records that document the monitoring and corrections of relevant sanitary conditions and practices during processing as required by 21 CFR 123.11(c).

Please notify this office in writing, within 15 working days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Tel. 718/340-7000 ext. 5507.

Sincerely,

  
Brenda J. Holman  
District Director